

**Health and Body Changes
(Health ABC)
Trial**

**DXA Quality Assurance Manual
for
Hologic QDR-4500
Bone Densitometers**

**UCSF DXA Quality Assurance Center
Department of Epidemiology and Biostatistics,
Division of Clinical Epidemiology, Box 0886**

and

**Osteoporosis Research Group
University of California
Department of Radiology, Box 0628**

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1.0 Introduction

The purpose of this manual is to describe the DXA bone mineral density (BMD) quality assurance program for the clinical centers participating in the Health, Aging and Body Composition study. It provides information specific to the Hologic QDR 4500 and is intended as a supplement to the Hologic Users' Manual.

To use this manual effectively, it is essential that to have read and understood the entire Hologic QDR 4500 User's Manual. The study densitometry operators are required to have participated in a Hologic QDR 4500 training session and should be familiar with all instrument features and procedures discussed in the Hologic Users' Manual.

During the study, any questions regarding procedures that arise should be directed to:

Health ABC DXA Reading Center
University of California, San Francisco
74 New Montgomery St., Suite 600
San Francisco CA 94105

Telephone: (415) 597-9287
Fax: (415) 597-9213

IMPORTANT: Unauthorized changes in scanner software or personnel can have a large impact on the integrity of study data. If, for any reason, changes in any of these areas are anticipated, please contact the DXA Quality Assurance Center in San Francisco in advance for further instructions.

2.0 Study Logistics

During the third year of the study, DXA scans will be acquired using the QDR 4500 as described below.

2.1 Overview of Scans for Year 3

DXA scans will be obtained on the QDR 4500 scanner provided for use in the Health ABC study. No other scanner should be used.

Scans will be acquired as follows:

A hip and whole body scan should be obtained on the QDR 4500 for all participants in the study.

2.2 Division of Quality Assurance Responsibilities

2.2.1 Clinical center responsibilities

The clinical centers must ensure the overall quality and completeness of the DXA data and that all protocols and procedures are strictly followed. Specific responsibilities include the following:

1. require that technicians are properly trained and certified;
2. identify a chief densitometry operator to train and supervise other operators;
3. perform and review daily QC scans and scheduled cross-calibration scans of traveling phantoms;
4. assure that proper archiving and back-up procedures for patient scans are performed and that archives are stored securely on optical disks until the end of the study;
5. at specified intervals, send the following materials to the Health ABC DXA Reading Center :
 - a. printouts of plots of the daily QC data
 - b. updated copies of patient scan and machine repair logs
 - c. original printouts of flagged scans

- d. original printouts of other requested scans
 - e. traveling optical disk with all newly acquired scan files obtained since the last data transfer
 - f. a copy of the current study database [DBARCHIVE] on a floppy disk
6. reanalyze centrally reviewed scans, as requested by the Reading center;
7. assure proper functioning of hardware and service from Hologic
- a. notify Hologic and the Health ABC DXA Reading Center of any machine or software problems, or if the QDR machine is being relocated
 - b. record machine/software problems and service on the “service log”
 - c. perform 5 QC phantom scans before, (if possible) and after service
 - d. perform 5 QC phantom scans before and after a machine relocation
8. contact the densitometry specialists at the Reading Center with any questions or problems which cannot be dealt with in the monthly batch mailings.

2.2.2 Health ABC DXA Reading Center responsibilities

The following are the responsibilities of the Health ABC DXA Reading Center:

- 1. write and maintain the quality assurance manual;
- 2. promptly review the daily QC phantom scan data received from each clinical center in order to identify surges or drifts in machine performance;
- 3. incorporate new participant data into the study wide database;
- 4. review certification and flagged scans and return results to each clinical center;
- 5. review random samples of scans from each clinic (from centralized database);
- 6. arrange for cross-calibration of all DXA instruments using traveling phantoms;
- 7. prepare quality control summary reports for Health ABC Steering Committee review;
- 8. identify possible sources of error, and suggest possible solutions. **(However, the Health ABC DXA Reading Center will not be responsible for the**

solution of a hardware or software problem; that will rest with the clinical center and Hologic.)

9. review and evaluate special purpose phantom scans;

Any questions or correspondence regarding the manual or the technical aspects of the DXA measurements should be directed to:

Health ABC DXA Reading Center
UCSF Prevention Sciences Group
74 New Montgomery, Suite 600
San Francisco, CA 94105

Phone: (415) 597-9287 FAX: (415) 597-9213

2.2.3 Hologic Responsibilities

The following are the responsibilities of the Hologic Inc.:

1. provide central training sessions for all Health ABC operators, if previously untrained (training to be paid for by the clinical centers);
2. provide hardware/software service within 24 hours, and work with clinic to resolve hardware or software problems;
3. work with the UCSF Quality Assurance Center in identifying and resolving any quality control or measurement problems.

2.3 Training and Certification of Health ABC DXA Operators

To obtain consistent results, the densitometry operators must be aware of possible sources of error that may affect data collection and analysis. Only those operators who have been certified through Hologic training and the Health ABC DXA Reading Center review are allowed to perform the scanning and analysis for this study.

Anyone performing scans for the Health ABC study must meet the following requirements:

1. read and understand both the Hologic QDR4500 manual and this manual;
2. successfully complete a Hologic QDR4500 training course;

3. satisfactory review of each operator's initial scans by the DXA Reading Center. In order for an individual technician to be certified to perform scans of a given skeletal site, the first 10 scans done on study participants at each skeletal site for each operator must be sent to the Reading center for review. Original printouts of scans should be sent to the Reading center at the address listed above as soon as the first 10 scans have been completed.
4. successfully pass the Reading center scan analysis tests;

It is the clinical center's responsibility to ensure that as new operators are brought into the study, all of the above certification criteria are met. Since the Hologic central training sessions are held infrequently, there may be several months delay between when a new operator is hired and when certification is complete.

Personnel not meeting these requirements may not scan participants without close supervision by a certified operator, unless specifically authorized by the Health ABC DXA Reading Center.

2.4 Health ABC DXA Reading Center Review of DXA Scans

Scan analysis quality will be ensured by a central review of analyzed participant scans. Whenever scans are to be reviewed centrally:

1. An original printout of the scan should be sent to the Reading Center.
2. It is the responsibility of the Health ABC clinic operator to reanalyze the scan according to the Reading Center comments and return a printout of the reanalyzed scan with an electronic copy to the Reading Center for verification.

Procedures for compiling and forwarding scans to the Health ABC DXA Reading Center are outlined in Section 5.

2.4.1 Flagged Scans

Any scans that appear unusual or difficult to analyze should be flagged for review by the Health ABC DXA Reading Center. Guidelines for flagging scans are listed in Section 3.4.

Flagged scans should be sent to the Reading center monthly with the updated patient database. Note the reason(s) for flagging on the Health ABC DXA Scan Log and on the original printout, for clarification of the problem.

The printouts will be reviewed for standard positioning and analysis procedures and returned to the centers with instructions for reanalysis, if appropriate. Often, these problem scans have been analyzed correctly and will not require further action.

2.4.2 Random Samples of Scans

Periodically during the study, a random sample of scans will be reviewed by the Health ABC DXA Reading Center. These scans will be sampled from the centralized database at the DXA Reading Center. The number of scans sampled will vary according to the period in the study, the number and training of the technicians and the results of previous samples.

3.0 DXA Scan Acquisition and Analysis

Standard scanning and analysis procedures for the whole body and hip bone density measurements are described in detail in the Hologic QDR 4500 Users' manual.

Some of the information from the Hologic manual is repeated in this document for emphasis. Please note, however, that some of the scanning evaluation protocols for this study differ from those detailed by Hologic.

3.1 Participant data

This section describes in detail the specific procedures to be conducted for the Health ABC study with respect to entering the patient biography, scanning the patient and analyzing the scans.

Prior to scanning each participant, a Health ABC Bone Density form should be completed for that participant.

Each participant visit will be assigned a visit code. This code should be entered on the Bone Density form and in the Comment field in the Patient Biography. Use 0 (zero) for baseline, 2 for the first annual visit, 3 for the second annual visit and so on.

3.1.1 Patient Biography

Care should be taken **NOT** to create a new biography when the participant returns

for repeat measurements

The following fields should be updated in the patient biography:

- Comment field – enter the number 3
- Operator scan code
- Weight

3.2 Whole Body Scans

The HOLOGIC Operator's Manual should be consulted for the proper whole body scanning and analysis procedures. Clarifications and exceptions for the Health ABC Study are noted below.

Whole Body Scanning

In the event that the participant was perfectly positioned at baseline (straight and centered on the table, no appendages cut – off), try to match this positioning as closely as possible.

3.2.2 Participant set-up

When performing whole body scans, attention has to be paid to the following points:

1. Have the participant remove all clothing, including shoes, and dress them in a hospital gown. Check that no metal or plastic objects remain in the scanning area. This includes hair clips and pins, underwire bras, snaps, zippers and buttons. Have the participant remove any jewelry, earrings, bracelets, watches, and rings.
2. Position the participant in the center of the scanning table with their head just below the head of the table. It is extremely important that the participant is correctly positioned dead center on the table. Match the positioning of the baseline scan as closely as possible. In those cases where baseline positioning was less than optimal, **DO NOT** duplicate the baseline positioning. Improve the positioning of the participant as best you can. **Pay particular attention to the positioning of the arms and legs.**
3. Place a loop of tape around the top of the feet so that the feet are straight (or slightly inverted) - this will help to prevent motion during the scan and bring the femoral necks into better position for scan analysis.
4. Verify that the participant is aligned with the scanner axis (solid line on the table).

If during scanning it is apparent that part of the participant's body lies outside the scan field, restart the scan.

5. The participant should be positioned as comfortably as possible since this reduces the chances of unwanted movements. In general, try to avoid using any pillows or blankets. If the participant feels uncomfortable in this position, you may use pillows for the head only after the upper half of the scan is done. You may then carefully place a pillow under the head of the participant without causing motion artifacts. This procedure should be practiced with the participant before scanning. If the participant cannot lie flat at all without the aid of a pillow (due to kyphosis), use a radio - lucent pillow.

6. If the participant is very tall, try to include their feet in the scan by placing their head near the very top of the table.

7. Instruct the participant not to move until the end of the measurement.

3.2.3 Whole Body Scan Analysis

When positioning the participant for their follow-up scan, it is helpful to have a printout of their baseline scan on hand for reference (or view the baseline scan on the workstation).

In order to evaluate the follow-up measurements, display the baseline scan using the COMPARE feature and compare it to your current image on the screen.

Match the location of the region markers as closely as possible to the baseline measurement. Optimally matched in this context means that the markers should be at the same position between the body regions as on the baseline image.

If adjustment cannot be done satisfactorily, reanalyze the baseline scan before proceeding with the COMPARE analysis. The Y2 scan will also have to be reanalyzed in COMPARE to the new baseline scan.

Scans that have metal or other artifacts should be flagged again at follow-up (even if the artifact was present at baseline and hasn't changed). If the only metal in the scan is due to the presence of a wedding band, there is no need to flag these scans. However, if there is a significant change in the amount of jewelry a participant is wearing, these scans should be flagged.

3.3 Hip Scans

The HOLOGIC Operator's Manual should be consulted for the proper hip scanning and analysis procedures. Clarifications and exceptions for the Health ABC Study are noted below.

NOTE: It is not necessary to send a copy of the baseline or Y2 scan on the traveling optical to UCSF unless you reanalyze these scans at the follow-up visit.

3.3.1 Hip Scanning

3.3.2 Participant set-up

Before scanning the participant, load the baseline scan onto the hard disk and have a printout of the baseline available. Refer to the baseline printout as you go through the positioning of the participant for the follow-up scan; this is to ensure consistent scanning of the same area. Careful positioning and visual comparison of the current scan with baseline are essential for producing precise measurements. Consistent projection of the femur is more important than the actual angle of the foot rotation. Use the rescan feature as soon as any positioning errors are detected during the current scan.

3.3.3 Analysis Procedures

High quality data analysis is strongly dependent on the ability to duplicate the placement of each of the four subregions of the hip. The Hologic analysis software calculates and displays all four regions using default values without any required operator interaction. The default size and location of these regions is usually not altered by the operator. However, to adapt them more closely to the optimal anatomic location for an individual participant, changes can be made as detailed in the sections which follow.

Load the baseline scan onto the hard disk. Display this baseline evaluation using the COMPARE feature along with the current scan to be analyzed. It is important to realize that proper comparison of a follow-up hip scan to its baseline depends upon maintaining the identical size and relative position of the region markers. Vertical or horizontal shifts of these regions by one or more pixels can greatly alter the final values of the analysis.

Global Region of Interest

1. The width and height of the global ROI must be the same as that used on the baseline.

2. The dotted lines from the baseline defining the bone region should overlay the follow-up as closely as possible. Occasionally there are small changes in adduction and rotation of the leg which were not eliminated by rescanning. The region surrounding the neck should have the best fit.
3. If the global ROI cannot be moved to the appropriate position because it is too large, the baseline scan will have to be reanalyzed with a properly reduced global ROI. Then the follow-up should be analyzed comparing it to the reanalyzed version of the baseline. Flag cases in which the baseline had to be reanalyzed.
4. **Use <Control> <End> to accept the global ROI and bone mask.**

Bone Edges If the ischium was deleted on the baseline scan, it should also be deleted on the follow-up scan. In the event that the ischium needs to be deleted on the follow-up scan but was not deleted on the baseline scan, the baseline scan should be reanalyzed to delete the ischium before completing the analysis of the follow-up scan.

Femoral Midline Unevenness (notches) in the upper or lower edge of the femoral neck can throw off the femoral midline so that it does not run down the center of the neck. This will in turn cause the femoral neck box to twist. If the midline looks like it might be off or the box is twisted on either the baseline or follow-up scan, it may be necessary to adjust the bone mask (e.g. filling in neck notches, deleting the ischium) in order to obtain appropriate positioning of the midline. The position of the midline itself should not be altered. If you have made changes to the scan such as filling in bone in order to alter the midline, or if the midline is still off, flag these cases for review by the UCSF.

Femoral Neck Box If the current location is optimally matched to the location of the neck box of the baseline analysis, use it unchanged.

1. If the current location is not optimally matched to the location of the neck box on the baseline, adjust the current region to achieve maximum correspondence. The size of the neck box must be the same on both baseline and follow-up.
2. If the current location cannot be satisfactorily adjusted while maintaining the same sized neck box, reanalyze the baseline within the constraints outlined above.
3. It is most important to have the neck box location and size correspond as closely as possible. If you cannot get the neck boxes to match, flag the scan for review.

Trochanteric Lines The trochanteric line should intercept the bone edge at the same

point on all scans. Matching is easily done during the compare analysis, especially since you will have the baseline to consult during the compare.

3.4 Excessive bone loss

Participants who lose a significant amount of bone mass during the study must be identified and appropriately counseled (see examples of letters to the physician and to the participant in Appendix B). To determine the annual loss or gain of bone mass, it is necessary to compare the results of the previous and the recent bone scans. The Hologic software provides a very convenient option to calculate the annual bone loss from two or more scans. The total hip is a region of interest where DXA measurements can be performed with a very high precision. Therefore, we will use this region for the determination of individual rate of change.

Determine the rate of change of all scans directly after the "Compare" analysis of the participant's scans.

1. Select the participant's Y3 visit scan using the *Select* menu.
2. After you have selected the scan go to the *Normals* menu (use arrow keys or type 'N' or type key 'F7'). The program will show you a list of participant scans available for plotting.
3. Mark the baseline and the Y3 visit scans that you want to plot by using the '+' key. Be sure to select the same scans used in the "Compare" analysis. After you have chosen the scans press the 'Enter' key. The screen now shows a new menu.
4. Select the menu option *Rate-of-change* using the arrow keys and press 'Enter'. A graph is now shown using the datapoints selected and the normal age range. Please notice that the rate-of-change graph will show an annualized BMD loss. **The value shown next to Total BMD must be multiplied by 2 to determine if the participant meets the excessive bone loss criteria.**

3.4.1 Confirming the presence of Excessive Bone loss

Excessive bone loss at the Y3 visit is defined as:

Decrease of **8** percent or more of the **TOTAL** hip bone mass (annualized loss of 4% or more).

1. If the rate of change indicated in the list below the graph meets or exceeds this percentage, the analysis of the follow-up scan should be repeated by the head QDR

operator.

2. If, after reanalysis the bone loss percentage still meets the EBL criteria, reposition and rescan the participant; then analyze the repeat scan using "Compare" to the baseline scan.
3. Recompute the annual rate-of-change as described above, marking with the '+' key the baseline and both Year 3 scans. The rate of change value will then be the average for the two scans.
4. If, after repeating the scan and recomputing the rate-of-change, the average BMD loss still exceeds the allowable limits, please complete the Excessive Bone Loss form and send the specified scans and printouts to UCSF. If excessive bone loss is confirmed by the DXA Reading Center, inform your Clinic coordinator. The Clinic coordinator should then inform the participant and the participant's physician (see Alert letters in Appendix B).
5. Whenever excessive bone loss is suspected, even if the value drops below the threshold on reanalysis or rescanning, baseline and follow-up scans should be flagged and immediately sent to UCSF for review. These should be separated from other flagged scans and marked "EXCESSIVE BONE LOSS."

3.5 Scan Flagging criteria

General

- Scan has unusual appearance or is difficult to analyze
- Any of the following in scan field (either in the bone or soft tissue)
 - Unusual anatomical variations
 - Surgical hardware
 - Patient motion during scan
 - Buttons, pins, zippers, pacemakers, vitamin pills, etc in scan ROI.
- ROI used on follow-up is different size than used at baseline
- Bone edges have been altered in any way
- Follow-up scans cannot be reasonably matched to baseline analysis

Hips

- Femoral midline misaligned and cannot be corrected by following the analysis procedures as outlined in the Health ABC manual
- Neck box width reduced from default
- Ward's triangle persistently located outside of Ward's region - difficulties in redefining search region
- Analysis program repeatedly fails to place regions appropriately - major operator interaction required for analysis
- Excessive bone loss

Whole Body

- Patient motion without rescanning (these scans are extremely susceptible to motion artifacts)
- Significant changes in positioning between baseline and follow - up scan.
- Unable to fit both arms in scan field

4.0 Scanner Quality Control

Monitoring of machine performance throughout the study is the joint responsibility of the individual clinical centers and the Health ABC DXA Reading Center.

4.1 Daily Phantom Scans

Perform the daily QC phantom scans as outlined in the Hologic manual. The results of these scans should be reviewed locally for abrupt changes in machine performance and the results sent to the Reading center once a month. Points of procedure to note:

1. Create only one patient biography per phantom. Avoid duplication of phantom biographies by using the patient menu to select the appropriate biography prior to scanning the phantom.

Scan the phantom on top of the pad. Ensure alignment with the scanner axis by using the laser cross - hairs.

Add the scan data to the QC database immediately after scanning and analysis are

complete.

4. Use the plot feature daily to verify that the BMD, BMC and AREA values of your scanner are within normal limits. If the most recent scan falls outside the limits, reposition the phantom and repeat the scan. **If the second scan also falls outside the limits, contact both Hologic and the Health ABC DXA Reading Center.**

5. After the phantom scan has been analyzed and added to the QC database, delete that day's scan from the hard disk. **Note: the Whole Body phantom scans and the ESP scans should be archived to an optical disk before being deleted from the hard drive.**

6. If the CV of the BMD exceeds 0.60% please contact both the Reading Center and Hologic to initiate appropriate action.

7. Check the system drift weekly by pressing <R> while viewing the plot. The slope of the calculated regression line should be within the range of the standard deviation shown. If the drift is greater than the standard deviation, contact both Hologic and the Reading center.

8. Generate a printout of the daily phantom plots (BMD, BMC and AREA) for the hip, spine and ESP phantoms once a week on your designated "QC day." This will facilitate detection of long-term drifts as well as short-term inconsistencies.

9. Original printouts including the scan results of the most recent daily phantom QC plots (BMD, BMC and AREA for hip, spine and ESP phantoms) are to be sent to the Reading Center for review monthly. The date range for the plots should cover the previous 6 months to the present.

10. Perform a dBarchive at least once a week.

In addition to the daily scanning of the Hologic spine phantom, a number of different phantoms will be used for Health ABC to monitor machine performance and for cross calibration purposes. The schedule for scanning these various phantoms can be found in the table below.

Phantom Scanning frequency

Local Hologic Hip phantom

2 times/week

Local Hologic Whole Body phantom
3 times/week (4500)

European Spine phantom
3 times/week
(every other month)

The European Spine Phantom will be rotated between the two clinics on a monthly basis.

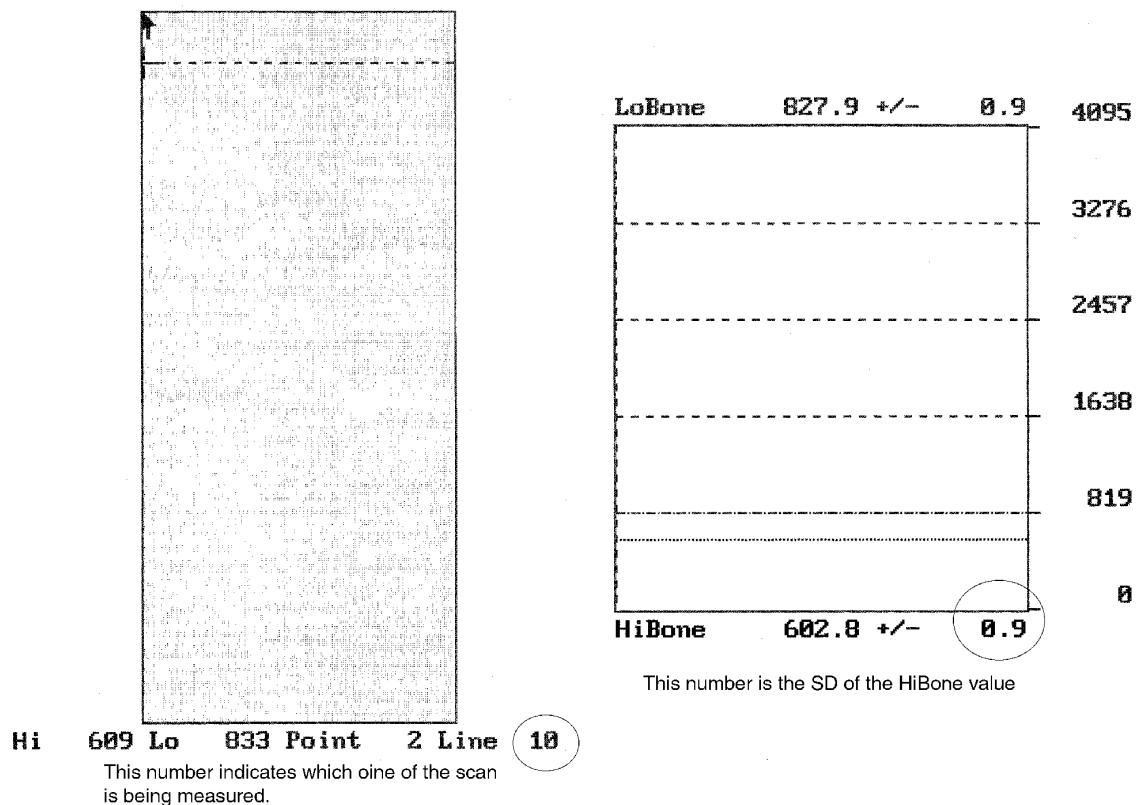
4.2 Whole Body Air Scan

A Whole Body scan of “air” (i.e. nothing on the table but a clean pad) should be performed once a week. The scan should be performed after the scan of the Body Composition Step Phantom.

The “air” scan will assess the proper functionality of the 4500A Whole Body scanner and indicate any potential problems with the x-ray beam, if present.

1. Clear the entire table top of any objects and clean the pad of any debris. Only the table pad should remain on the table. This is critical since the test can detect items as thin as a single piece of Scotch tape.
2. Enter a Patient Biography as **WB AIR QC SCAN**. Enter the system serial number in the Pat ID field. Leave the remaining fields blank. Press <F10> when completed. Please be certain to use this biography for all future WB air scans.
3. Perform a scan by choosing “whole body” from the Scan menu. Scan the entire length of the table. Do not interrupt the scan; perform a complete scan.
4. With the air scan selected, <ESC> to the Main Menu. Choose the UTILITY option and press <ENTER>. Then choose SERVICE and then PLOT. A blank image will appear. Press the <PgDn> key once to move to line 10.

The image will appear along with a graph. At the bottom of the graph an indicator of the reference wheel segment that produced the data will appear along with an attenuation value +/- a SD(Standard Deviation). See diagram below.



For example:

HiBone 543.3 +/- 0.9

The last value, 0.9, is the value we want to record. It represents the SD of the air values across a scan line. The value should not exceed 2.0 units. Use the <DOWNARROW> key to view (9) additional lines to obtain a better estimate of the SD. Record all 10 SD values for HiBone for lines 10 through 19 on the worksheet.

**WHOLE BODY AIR QC SCAN
WORKSHEET**

Clinical Center:

Serial Number:

LINE	SEGMENT	SD
10	HiBone	
11	HiBone	
12	HiBone	
13	HiBone	
14	HiBone	
15	HiBone	
16	HiBone	
17	HiBone	
18	HiBone	
19	HiBone	

Date:

Signature:

5. Press the <PRINTSCREEN> key to obtain a paper copy of the plotted data. Archive the WB AIR QC SCAN to your clinic opticals and COPY the scan to your traveling optical.

****In the event that the SD exceeds the limit of 2.0 units, immediately fax the worksheet to Eddie Yapchian at Hologic (FAX 781/ 890 – 0863) and to Maurice Dockrell at UCSF (FAX 415/ 597 – 9213)**.**

7. Archive the scan to your clinic optical and copy it to your traveling optical.

4.3 Cross-Calibration of Scanners

In order to accurately assess absolute variations in scanner performance between clinical centers, periodically throughout the study phantoms will be either mailed or brought to each of the field centers and scanned. The Hologic hip, spine and block phantoms, Whole Body phantom and the European Spine Phantom (ESP) will be used. A detailed protocol will accompany the phantoms.

4.4 Machine, Software and Service Problems

If your machine needs to be repaired or if any adjustment has to be made that possibly might affect your data:

1. Do a dBarchive before any work is done on your QDR.
2. Contact the Reading Center before the repairs or adjustments are made to find out whether additional measures are required.
3. Perform 5 scans of the Hologic daily QC spine phantom before (if possible) and after the repairs or adjustments are made.
4. After repairs or adjustments are completed, send the repair technician's notes and a copy of the completed study repair log to the Health ABC DXA Reading center. The repair log should contain complete information on all repairs done on your machine. Please keep a repair log with your machine.

4.5 Software Change Control

Unauthorized software changes must be avoided. If for any reason you think you have to change the software, or your Hologic service representative recommends a software change, contact the Health ABC DXA Reading center before any changes are made.

The system software installed on the Health ABC QDR 4500 densitometers should be Version 9.03. You can find your version number at the top of the blue Hologic menu. It will say "Hologic QDR 4500 version 9.03". Future software upgrades will be checked by the UCSF Quality Assurance Center in conjunction with Hologic technical support personnel to assure that the upgrade will not adversely affect the study. Authorized upgrades must be cleared by the Health ABC DXA Reading Center before installation at the study sites.

5.0 Data Management

5.1 Hard Copies of Scans

The study site is responsible for maintaining original hard copies of all scans performed during the study. Keep the original printouts in the participant's scan printout folder. The following printed report is needed for each scan:

Hip: print the standard report.

Whole body: print the BMD and body composition reports (2 pages).

5.2 Electronic Scan Archive

For scan archival, each study site works on a two optical disk system. (There will also be two “traveling opticals” for sending scan images for central review.) Both optical disks are continually updated at the end of each day using the Optical 1 and Optical 2 options under the Hologic archive menu. Please be sure to rearchive any scans that you reanalyze after you have completed the reanalysis. In order to use the optical disks efficiently, do not save or archive scans individually. Saving scans in batches (e.g. at the end of a day) will ensure the longevity and efficient usage of the optical disk space. The QDR software will give a warning message when optical capacity has been reached. Fill side A of the disk first, then fill side B. (See the Hologic User’s Manual for detailed instructions.). The ODC2 should be a dedicated Health ABC optical, used only for archiving scans acquired for Health ABC.

Scans to be archived **each day** to the Optical 1, Optical 2 and “traveling” optical disks include:

1. all new participant scans acquired since the last archive was performed;
2. all scans that have been reanalyzed since the last archive; (Note that if a scan needs to be restored and reanalyzed for any reason, it will need to be rearchived.)

Optical 1 and 2 will remain at the study site at all times. (The “traveling opticals” will be sent back and forth between the study site and the Health ABC DXA Reading Center.)

The clinical centers are responsible for following the archive schedule and for keeping the optical disk archives safe until the end of the study.

5.3 Transfer of Data to the Health ABC DXA Reading Center

The following items are to be sent to Reading center at the end of each month:

1. QC PRINTOUT. Send printouts of the most recent plots of the QC database, (BMD, BMC and AREA) for the hip, spine and ESP phantoms . The plots are reviewed at Reading Center, and problems are reported back to the clinic.
2. PARTICIPANT SCAN LOG. Send a copy of the written patient scan log sheet covering participants scanned since the last data transfer. Use the log sheets to “flag” individual scans for review at the Reading Center.
3. SCANS FOR REVIEW. Send original printouts of certification scans, “flagged” scans, and any scans requested for review by the Reading Center. Please write the reason the scan was flagged, requested or being sent directly on the printout. These scans will be triaged visually based on the original printouts and analyzed on the Hologic workstation if necessary.
4. TRAVELING OPTICAL DISK. Send electronic copies of all scans acquired and reanalyzed since the last data transfer. Archive scans using the COPY feature. Do not archive the scans individually, as this will use up the disk space rapidly.

NOTE: Do not send a copy of the baseline scan on the traveling optical to UCSF unless you reanalyze the baseline scan at the follow-up visit.

5. REANALYZED SCANS. Send original printouts of all scans which have been reanalyzed according to the DXA Reading center instructions since the last data transfer. Attach the annotated printouts sent by the coordinating center which indicated the problems requiring reanalysis. You MUST also send back the reanalyzed scan images on the traveling optical.
6. DB ARCHIVE patient database (on floppy disk). Please include the following on the disk label:
 “DB ARCHIVE”
 batch #
 clinic name
 date (end date of 1 month period)
 if more than 1 disk, label each disk as above and 1 of 3, 2 of 3, etc.

Diskette Label for DB Archive

Health ABC
DB Archive

Date ____
Clinic ____
Batch # ____
Diskette No. ____ of ____

Please note: The Reading center will use the most recent scan data for participants whenever there are multiple analyzed scans from the same date in the data base. Please notify us if there are exceptions to this.

7. Copy of the Maintenance/Repair Log (with a copy of the Hologic service report).

Pack the materials carefully. The optical disk should be placed in a plastic bag and then wrapped in plastic bubble wrap to avoid damage. Batches containing the optical disk should be send via FedEx/UPS.

Assign a number to each batch of BMD data, complete the BMD Batch Checklist, indicating the number and which materials are included in the batch, and send it along with the batch materials.

The materials in the batch should be bundled separately by type.

Ship these items monthly to the following address:

Health ABC DXA Reading Center
UCSF Prevention Sciences
74 New Montgomery, Suite 600
San Francisco, CA 94105

5.4 Return Materials Sent by the Reading Center

The Health ABC DXA Reading Center will return the following items to the study site after review:

1. Annotated printouts of flagged scans, random sample scans, and any other requested scans are returned to the study site with explicit instructions for reanalysis, as necessary. The clinic then reanalyzes the problem scans according to the Reading Center recommendations. The reanalyzed scan is then saved and rearchived and the database at the study site is automatically updated. An original printout of the reanalyzed scan is sent to the Reading Center with the next data transfer to verify compliance.

2. Traveling optical.
3. Any recommendations for service, additional phantom scans, etc., as necessary based on the quality control database.

APPENDIX A. STUDY FORMS

The following forms are included in this Appendix:

Batch Record Form

Bone Density Form

Hologic Maintenance/Repair Log Sheet

DXA Scan Logs

Excessive Bone Loss Form

Master copies of the forms will be mailed directly to your site. Always keep a copy of any form you send to the HABC DXA Reading Center

BMD Batch Record Form

HEALTH ABC

BMD BATCH RECORD FORM

Batch Number: _____	Date Batch Mailed: ____/____/____ <div style="text-align: center; font-size: small;"> Month Day Year </div>
----------------------------	---

Clinic Name: _____

Contents: (check Yes or No)

DB Archive Disk	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Date Archived: ____/____/____ <div style="text-align: center; font-size: small;">Month Day Year</div>
QC DB Printout	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Date Printed: ____/____/____ <div style="text-align: center; font-size: small;">Month Day Year</div>
Scan Log Sheet	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Flagged Scans	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Number: _____
Reanalyzed Scans	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Number: _____
Random Sample Scans	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Number: _____
Other Scans	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Number: _____
(specify: _____)			
Traveling Optical	<input type="checkbox"/> Yes	<input type="checkbox"/> No	

Certification Scans:

Staff ID	Number of Scans	Scan Type
_____	_____	_____
_____	_____	_____
_____	_____	_____

Staff ID#: _____

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Bone Density (DXA) Scan Form
(page 1 of 2)

HABC Enrollment ID #	Acrostic	Staff ID #
<div></div>	<div></div>	<div></div>

BONE DENSITY (DXA) SCAN

- ① Do you have breast implants?
- ☐ Yes ☐ No ☐ Don't know ☐ Refused

- ♦ Flag scan for review by DXA Reading Center.
- ♦ Indicate in the table in Question #4 whether breast implant is in "Left ribs" or "Right ribs" region.

- ② Have you ever had a hip replacement surgery where all or part of your joint was replaced?

☐ Yes ☐ No ☐ Don't know ☐ Refused

On which side did you have hip replacement surgery?

☐ Right

☐ Left

☐ Both

Do NOT scan right hip.

Do NOT scan left hip.

Do NOT scan either hip.

- ③ Which hip was scanned at the Baseline (Year 1) Clinic Visit?
(Examiner Note: Refer to Data from Prior Visits Report to see which hip was scanned at Baseline-Year 1.)

☐ Right

☐ Left

☐ Neither

Scan right hip unless contraindicated.

Scan left hip unless contraindicated.

Scan right hip unless contraindicated.

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Bone Density (DXA) Scan Form

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BONE DENSITY (DXA) SCAN

- 4 Do you have any metal objects in your body, such as a pacemaker, staples, screws, plates, etc.?
- ☐ Yes ☐ No ☐ Don't know ☐ Refused

- a. Flag scan for review by DXA Reading Center.
- b. Indicate the location of joint replacement, hardware or other artifacts (sub regions are those defined by the whole body scan analysis.)

Sub	Hardware	Other Artifacts
i. Head	<input type="radio"/>	<input type="radio"/>
ii. Left arm	<input type="radio"/>	<input type="radio"/>
iii. Right arm	<input type="radio"/>	<input type="radio"/>
iv. Left ribs	<input type="radio"/>	<input type="radio"/>
v. Right ribs	<input type="radio"/>	<input type="radio"/>
vi. Thoracic spine	<input type="radio"/>	<input type="radio"/>
vii. Lumbar spine	<input type="radio"/>	<input type="radio"/>
viii. Pelvis	<input type="radio"/>	<input type="radio"/>
ix. Left leg	<input type="radio"/>	<input type="radio"/>
x. Right leg	<input type="radio"/>	<input type="radio"/>

- 5 Have you had any of the following tests within the past ten days?

	Yes	No
a. Barium enema	<input type="radio"/> *	<input type="radio"/>
b. Upper GI X-ray series	<input type="radio"/> *	<input type="radio"/>
c. Lower GI X-ray series	<input type="radio"/> *	<input type="radio"/>
d. Nuclear medicine scan	<input type="radio"/> *	<input type="radio"/>
e. Other tests using contrast ("dye") or radioactive materials	<input type="radio"/> *	<input type="radio"/>

(* Examiner Note: If "Yes" to any responses above, reschedule bone density measurement so that at least 10 days will have passed since the tests were performed.)

- 6 Was a bone density measurement obtained for...?

a. Whole Body ☐ Yes ☐ No

Last 2 characters of scan ID #:

Date of scan: / /

Month Day Year

b. Hip ☐ Yes ☐ No

Last 2 characters of scan ID #:

Date of scan: / /

Month Day Year

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HABC Maintenance & Repair Log Sheet

HABC MAINTENANCE & REPAIR LOG SHEET

Clinic name: Date:

1. Describe problem (incl. dates):
.....
.....

2. Did problem affect scans or BMD data?

☐ Yes ☐ No

If yes, describe:
.....
.....

Did problem cause downtime of scanner? ☐ Yes ☐ No

If yes, for how long?.....

3. Describe the action taken by you (including repair by Hologic)?
.....
.....

4. Was the problem resolved?

☐ Yes ☐ No

If not, please specify:.....
.....

5. Was a recalibration of the device necessary?

☐ Yes ☐ No

6. Were phantom scans performed after the repair or the recalibration?

☐ Yes ☐ No

If yes, did you notice a change in the phantom BMD values?

☐ Yes ☐ No

Please fill in the form thoroughly. Send one copy together with the technician's repair invoice to the UCSF QA Center. Keep one copy with your scanner in your own repair log.

HABC DXA Y3 Scan Log 4500

Clinic:			HABC Y3 DXA Scan log		QDR 4500
Date	Pat ID	Acrostic	Scan Type	Scan #	Flagging Comments
			Whole Body(Y3)		
			Whole Body(Y1)		
			Hip(Y3)		
			Hip(Y1)		
			Whole Body(Y3)		
			Whole Body(Y1)		
			Hip(Y3)		
			Hip(Y1)		
			Whole Body(Y3)		
			Whole Body(Y1)		
			Hip(Y3)		
			Hip(Y1)		
			Whole Body(Y3)		
			Whole Body(Y1)		
			Hip(Y3)		
			Hip(Y1)		
			Whole Body(Y3)		
			Whole Body(Y1)		
			Hip(Y3)		
			Hip(Y1)		
			Whole Body(Y3)		
			Whole Body(Y1)		
			Hip(Y3)		
			Hip(Y1)		
			Whole Body(Y3)		
			Whole Body(Y1)		
			Hip(Y3)		
			Hip(Y1)		

HABC Excessive Bone Loss Form



HABC Enrollment ID #	Acrosite	Date Form Completed	Staff ID #
H		Month / Day / Year	

EXCESSIVE BONE LOSS FORM**Suspected Excessive Bone Loss Checklist**

(Examiner Note: Please make sure that this form is accompanied by all the items listed below.)

- ☐ Printouts of the baseline and all follow-up scans of the hip
- ☐ Printouts of the "rate of change" report(s) you created for the hip
- ☐ Copies of baseline and all follow-up scans of the hip on floppy disk

Be sure to follow all procedures for participants with suspected excessive bone loss.

Comments: _____

To be filled out by the UCSF DXA Reading Center

- ☐ Yes, we can confirm excessive bone loss.
The scans are technically correct and the analyses are performed appropriately.
- ☐ Yes, we can confirm excessive bone loss.
However, the scans were not analyzed properly. Please reanalyze the scan(s) following our instructions and inform the participant of the correct bone loss %.
- ☐ The scans provided indicate possible excessive bone loss.
However, a second scan of the site was not performed in this participant. Excessive bone loss can only be confirmed after you have obtained a second scan of the region where bone loss is suspected. Please schedule the participant for a repeat measurement.
- ☐ After scan review we cannot confirm excessive bone loss.

Comments: _____

Signature of UCSF DXA Reading Center Reviewer _____ Date: _____

Draft



Version 1.0, 4/1/99

APPENDIX B. Excessive bone loss alert letters

March 13, 1999

Jane Doe
1234 Market Street
Pittsburgh, PA 15213

Dear Ms. Doe:

During your last clinic visit for the Health ABC study, we repeated measurements of your hip bone density. Analysis of the results indicated that you have lost bone in the hip at a rate greater than 4 % per year since your baseline measurement was made.

This loss is greater than average for a person your age and may indicate an increased risk of fracture. This bone loss may also be related to other health conditions, or could result from use of certain medications.

We have enclosed both copies of your hip scan, your baseline measurement and your last measurement. We suggest that you consult with your personal physician to find out why this is occurring, and we would be happy to forward these results to your doctor.

If you do not have a source of medical care, we can provide you with the name of a physician who specializes in treating osteoporosis in Pittsburgh.

Thank you for your time and interest in the Health ABC study. Please do not hesitate to call us if you have questions at () _____ and ask for _____.

Sincerely,

Anne Newman, M.D., MPH
Health ABC Principal Investigator

Marguerite Meyer, RN, MEd
Coordinator of Clinical Studies

/sa

March 13, 1999

Abe Friedman, M.D.
5845 Centre Avenue
Pittsburgh, PA 15213

Dear Dr. Friedman:

Your patient, _____, who has been a participant in the Health ABC study for the past 3 years, was here on ____/____/____ for their annual visit. We have measured bone mineral density of the hip with state-of-the-art densitometry machines at baseline and approximately 2 years later. The BMD scans of their total hip showed ____% bone loss since 2 years ago. Our study experts have reviewed these scans and believe the bone loss to be real. This is considered to be a significant amount and is referred to as "excessive bone loss" by our study. Significant declines in hip BMD may indicate the presence of an important medical condition, such as vitamin D deficiency or multiple myeloma.

We are enclosing a copy of the participant's hip scan and reference plots that show the bone loss to be ____%.

If you have any questions, please feel free to contact us at (____)_____.

Sincerely,

Anne Newman, M.D., MPH
Health ABC Principal Investigator

Marguerite Meyer, RN, M.Ed.
Coordinator of Clinical Studies

/sa

APPENDIX C. CROSS CALIBRATION PHANTOM PROTOCOLS

The following protocols are included in this Appendix:

European Spine Phantom Protocol

Whole Body Phantom Protocol

DXA Scanner Cross-Calibration using the European Spine Phantom (ESP)

European Spine Phantom (ESP) Scanning

1. Create a Patient Biography in the following manner.

Name : **ESP 123**

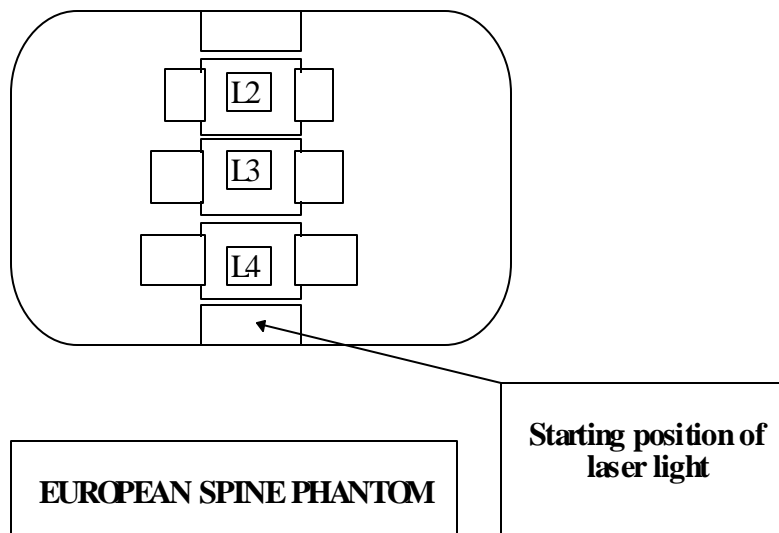
Pat ID : Enter the phantom serial number.

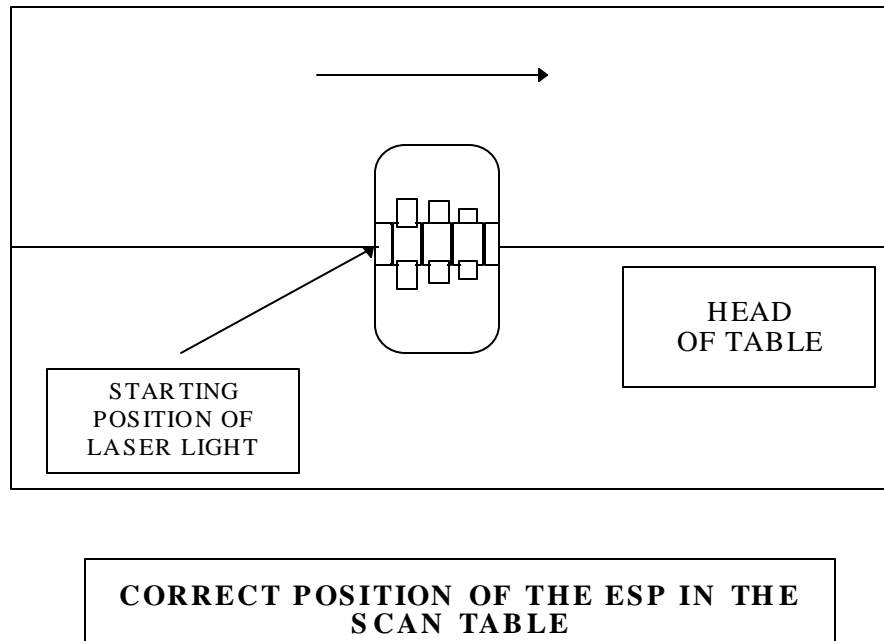
Please use zeros (Ø) in the biography and not the letter "O".

All other fields in the Patient Biography should be left blank.

2. Place the ESP on the mat. Make sure it is straight on the table.

Use a ruler to align the phantom and move the cross hairs head to foot along the length of phantom to check the alignment.





3. Go to the scan menu <F3> and choose "Spine". Then select the default '**Array Spine**' as the scan type. After the arm moves to the back press <Enter>. The arm will move forward to the correct centering point for the scan.
 4. Move the arm to center the red laser positioning light over the black line on 'L5' of the ESP. Note that the ESP consists of only 3 complete vertebra (L2, L3, L4).
- Set scan length to 4 inches** or approximately 10 cm.
5. Press < **F2** > to Scan.

Use < **F3** > (rescan) if the Phantom is not centered or does not have all vertebrae visualized.

Allow the scan to finish on its own; please do not stop it prematurely.

Creating a European Spine Phantom (ESP) Baseline Analysis

1. Select Region of Interest (ROI).
 - A) The width of the ROI should be 116 pixels. The ROI height should be 87.
 - B) Center the ROI so the Spine Phantom is in the middle.
 - C) Ensure that the intervertebral markers lie within the intervertebral spaces.

Press <**End**>.

2. Mark Inter vertebral Spaces.

Be sure the lines are centered in the spaces between each vertebrae. They must not intersect any of the vertebral bodies.

Press <**End**>.

3. Label Vertebrae.

- A) Label the vertebrae L2 - L4.

Press <**End**>.

- B) At this point, the QDR begins its calculations of the soft tissue and bone thresholds. Wait until the calculations are completed before processing any further.

4. **DO NOT INSERT OR DELETE ANY POINTS.**

Press <**End**>.

5. Print the Report Screen.
6. Add the scan to your QC database.
7. Archive the baseline scan to an optical or floppy disk.

European Spine Phantom (ESP) Compare

1. Once a baseline European Spine Phantom scan has been established, use that scan as the reference scan within the Compare feature menu for all subsequent scans.
2. After a subsequent scan has been performed, choose Compare at the Analyze menu.
3. Highlight the baseline European Spine Phantom scan and press **<ENTER>**
4. Analysis.
 - A) Two images are displayed on the screen. The one on the left is the present scan.
 - B) The ROI and bone outline are automatically placed over the scan. Using the arrow keys, move the entire box so it matches as best as possible over the image. When comparing spine scans, move the ROI up and down or left and right as necessary.
Press **<End>**.
 - C) Mark Intervertebral Spaces. If the ROI was matched correctly, no adjustment should be necessary.
Press **<End>**.
 - D) Label Vertebrae (L2 - L4). This is done automatically.
Press **<End>**.
At this point, calculations begin. Please do not interrupt them.
 - E) **DO NOT INSERT OR DELETE ANY POINTS.**

Press **<End>**.
 - F) The Report Screen is generated.
 - G) Add the scan to your QC database

Whole Body Phantom Protocol

I. PHANTOM ASSEMBLY

Before lifting or transporting the phantom, break it down into its individual components. Use care, the impact force of a phantom component dropped from table height can cause severe injury, particularly if the impact is delivered through one of the phantom's beveled edges. Having another person help move the phantom components is strongly recommended.

A thin, gray PVC sheet is attached to the large white plastic piece that contains the two plastic locating pins. This HDPE/PVC combination is the bottom layer (base) of the phantom. Position it on the scanner table such that the PVC is on the bottom (i.e. the gray PVC is in contact with the table pad and the two plastic locating pins project out of the plane of the table towards the ceiling.

Place the second large white plastic piece on top of the phantom base, using the locating pins as a guide. The second piece should be placed such that the beveled edge forms a "V" with the base.

Next, place the medium size white plastic pieces on the phantom, again forming a "V" with the two beveled edges of the middle pieces. Then place the small white plastic pieces on top, forming another "V" with the small pieces. The final assembly will form a pyramid (see Figure 1, side view). This is the only valid configuration for the phantom measurement. All other configurations including adding materials to the phantom, removing pieces of the phantom, scanning the phantom upside down, etc. violate the intended use of the phantom and may produce invalid results.

II. PHANTOM POSITIONING

Carefully position the whole body phantom in the center of the scanner table with the head of the phantom at the head of the table. Allow 24" (61cm) of empty air space at the head of the table. Carefully position the phantom parallel with the long axis of the table, using the table pad markings as a guide. When properly centered, there will be a constant 3.5" (8.9 cm) gap between the side of the phantom and the front and back limits of the 4500A scanner table (see Figure 1).

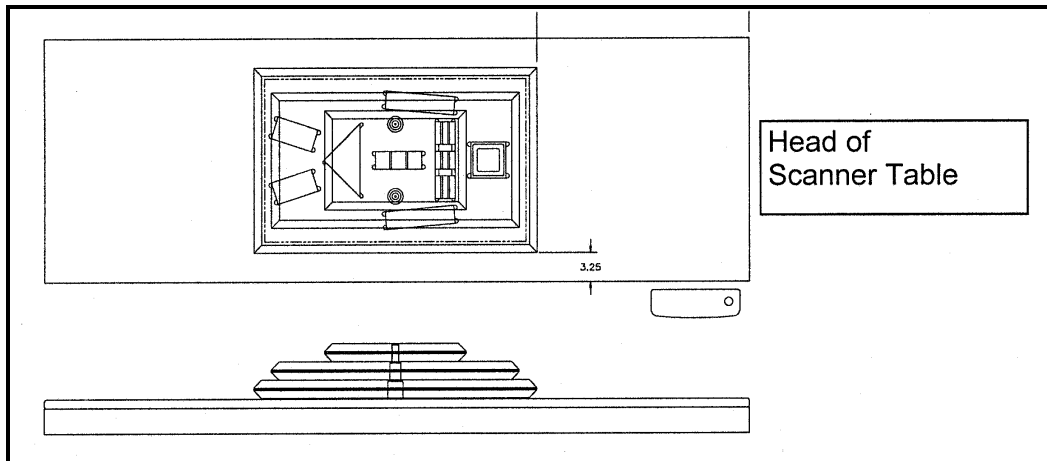


Figure 1. Layout of Whole Body Phantom positioned on the 4500A scanner table. Also shown, the fully assembled phantom viewed from the side. (Note that the amount of empty space between the side of the phantom and the sides of the table will vary depending upon scanner model).

III. DATA ACQUISITION - SCANNING THE WHOLE BODY PHANTOM

Make sure that the phantom is centered, is parallel to the long axis of the table and is correctly oriented with respect to the head of the table.

Enter **"WB PHANTOM #xxx"** in the Patient Name field of the Patient Biography (where **xxx** is the serial number of the Whole Body Phantom).

Remove all artifacts from the table surface. Extraneous objects in the scan field will interfere with the measured results in an unpredictable fashion.

Select the standard Adult Whole Body scan mode commonly employed at your facility. Accept the default scan length and scan width. Perform a complete scan of the entire table surface including the phantom. Do not interrupt the scanner during the measurement.

Carefully inspect the scan image to ensure that the phantom was (i) centered, (ii) parallel to the long axis of the scanner table and (iii) the phantom's head appears at the top of the image. If the scan image appears satisfactory, proceed to the analysis section. If not, carefully reposition the phantom according to the instructions in Section II and repeat the scan.

IV. ANALYSIS

A. General Comments

The goal of the analysis is to carefully delineate the various body regions in a

standard and reproducible fashion, so that measured results will reflect instrument performance, not variations in analysis techniques. Of particular importance are the placement of the head ROI cutline and the cutlines that delineate the ribs, since these two regions affect global body composition and BMD. It is essential that the baseline measurement is technically adequate and that the analysis is performed by direct comparison to the sample analysis on the Hologic diskette labeled: "SAMPLE ANALYSES: WB PHANTOM".

B. Specific Instructions - Hologic QDR systems

Follow the instructions in Sections II and III to acquire a technically adequate scan of the Whole Body phantom. Restore the appropriate scan from the Hologic diskette labeled "SAMPLE ANALYSES: WB PHANTOM" to the analysis workstation. (See Table 1 for the correct scan to restore for your QDR model). Select the newly acquired WB Phantom scan. Then use the Compare feature to register the ROI cutlines of the Sample scan to the newly acquired scan of the WB Phantom. Once the ROI's have been matched as nearly as possible, complete the analysis and print the first and last pages of the report.

Archive the baseline measurement for safekeeping but do not delete it from the analysis workstation. All future whole body phantom measurements will be compared to the initial baseline measurement. After the initial measurement, the sample scan restored from the sample diskette should be deleted.

QDR MODEL # WB PHANTOM SCAN (RESTORE FROM SAMPLE DISK)

1000W, 1500, 2000 Pencil beam

1000/1500/2000 Pencil WB Phantom

2000 Fan Beam

2000 Fan WB Phantom

4500W

4500W WB Phantom

4500A

4500A WB Phantom

Table 1. Scans to restore for a given QDR model #.

V. INTERPRETATION OF MEASURED VALUES

The phantom measurements should be printed out and placed in a log book. The values for Total BMD and %Fat should be manually plotted on the graph supplied

by the HABC DXA Reading Center.

